Clinical supply chain management is not an easy job. It is a career suited to creative and decisive individuals that work well under pressure with imperfect information. Asked to predict what can seem unpredictable, supply chain managers (SCMs) must plan for optimistic enrolment rates in an expanding global network of clinical sites and regional depots with increasingly complex, scarce and expensive drug products while under scrutiny for overages and bottom lines.

SCMs forecast drug supply for three scenarios: what should happen, what could happen and what is happening. It can be a nerve-wracking and thankless job, mostly recognised when things go wrong. Lately, however, it has become less painful, largely thanks to advances in forecasting and simulation technology, as well as enhanced integration with interactive response technology (IRT) and material-resource-planning (MRP) systems. These improvements boost forecast accuracy and shorten the gap between the planner and study trends, easing SCMs’ hardship.

In early planning, before first patient in (FPI), clinical-supplies forecasting has traditionally been more about creating flexibility than achieving accuracy. Assumptions provided in the planning stages of a study would likely change when the rubber hit the road. So, devising a supply strategy that allowed faster or slower enrolment by region, without over committing investigational medicinal product (IMP), was essential.

Coming up short on patient demand was a greater risk than trashing supply that wasn’t used when enrolment was slow; so overage was usually high. But the industry is not only talking about small molecules anymore.

**Better forecast accuracy**

These days, limited availability of biological medicines, cost-prohibitive comparators and shortened shelf lives drive supply strategies as much as patient demand does. This new paradigm requires better forecast accuracy without compromising on flexibility. This is what makes simulation technology so powerful.

"The need to have full visibility of the data governing the clinical supply chain is paramount. In partnering with N-SIDE, we believe that we can provide the most complete physical and digital supply chain to the market, improving the supply of innovative medicines to patients."

– Robert Dunlop, president and managing director of Almac Clinical Services

Simulation solutions built with the latest advanced analytics techniques provide critical and timely information to SCMs that examine the risks and costs associated with various supply strategies. Different combinations of IRT settings, production plans and depot replenishments are simulated in order to identify the optimal fit strategy.

Variability and unpredictability, as found in clinical trials, are replicated in solution algorithms, allowing an accurate assessment of the risk for any strategy. Even complicated titration schemes and weight-based dispensing can be modelled and simulated. SCMs can compare different strategies with quantified results that substantiate early supply decisions and improve communication across departments.

Equipped with Monte Carlo simulation results that consider thousands of enrolment scenarios and various IRT settings, SCMs build baseline forecasts and hurtle confidently towards FPI, ready for anything.
Enrolment commences and SCMs monitor study activities, update forecasts to stay aligned with trends, and adjust resupply numbers and IRT table values to conserve drugs or reduce shipments. Chances are that by the time the first patient enrolls, SCMs are so busy planning for the next study that monitoring may be neglected. Perhaps, the available bandwidth supports a bi-monthly slog through IRT reports to trend enrolment, track inventory, coordinate depot shipments and recalibrate bulk and finished goods manufacturing schedules. It is tough work, but it doesn’t have to be. After all, the data is in the IRT, SCMs just need to get it back into forecasting or simulation tools. So, how do SCMs get these systems talking to one another?

"We’re thrilled with our partnership with Almac. This will further broaden the delivery of innovative solutions to our clients, bringing excellence in risk management and cost reduction to the whole clinical trial supply chain."

– Jacques Parlongue, N-SIDE CEO

IRT’s have long-used secure file transfer protocols (SFTPs) and/or web service files when conducting clinical trials. Chances are that each consignment raised for a clinical site shipment at a CMO is raised through SFTP or web service. Likewise, dispatch, receipt and acknowledgement files are flying back and forth between company servers, providing up-to-the-minute information about the status and location of drug supply. SCMs use these same files to transfer site and patient events data from IRT systems to forecasting and simulations technology. Every day, patient events – screening, randomisations, dosing visits, titrations and discontinuations – are uploaded to MRP and forecasting systems through SFTPs to adjust demand based upon events, modified predictions and available inventory, creating up-to-the-minute forecasts.

SCMs no longer need to plod through IRT reports for data to adjust forecasts. When systems are well integrated, the files are all set up, the data comes in nightly and the forecasts are adjusted. SCMs just have to look.

When change happens, resimulation allows SCMs to examine hundreds of different strategies, assess feasibility, influence clinical teams and limit patient impact.

Multiple regional depot supply strategies are tested against fixed production plans, and simulation results pinpoint when and where risk will occur with each strategy. Here the supply chain manager is armed with accurate simulation results to inform and assist in the decisions on how to address a change of plans.

Of course, SCMs remain in control by weighing options and collaborating with clinical, regulatory, logistics and CMC partners while analysing simulation results, rationing supplies and strategically placing new comparator orders. SCMs still fly the plane, but they employ a more accurate and precise instrument panel to do so, which prevents over-exposure, limits risk and carefully adjusts inventory management settings within the IRT to balance risk with cost.

SCMs also have access to a more experienced flight crew, comprised of consultants that provide a comprehensive service in support of the clinical supply chain.

**Stronger and smarter supply chain**

Almac and N-SIDE have formed a partnership combining experienced consulting staff, simulation and forecasting technology, and integration with IRT and MRP systems. The companies have found that this collaboration makes use of the right experience and tools. Almac SCM consultants work with N-SIDE consultants and advanced analytics experts to examine study assumptions, variables, risk and cost. SCMs use the resulting simulation reports to refine forecasted supply strategies and optimise IRT medication management settings.

Informed by N-SIDE simulations results, a baseline is created in forecasting modules of the Almac MRP system, which is integrated with IRT data by way of SFTPs. Patient, site and drug events update nightly and incrementally adjust the study forecast. This means that SCMs’ oversight of study supply is informed by the current data, but without manual retrieval from IRT reports. Almac SCM and N-SIDE consultants meet regularly with clients to examine trends or major changes, resimulating when warranted. The result is a supply plan that achieves accuracy and flexibility with less tedium and fewer gut checks.

While they may never have all of the information that they ideally would like to make clinical supply decisions, by blending integrated technologies with experienced human oversight, supply chain professionals are well-informed. When experts collaborate using the latest technology and integrated systems, they build a stronger and smarter clinical supply chain.

**Further information**

N-SIDE
www.n-side.com

Almac Group
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